Clinical Leukopak and Whole Blood Specifications

stemexpress^{*}

Clinical Donor Eligibility		Clinical Capabilities		
			Leukopak, Fresh	Whole Blood, Fresh
Donor Characteristics	Healthy donors, age 18-65 years old Backup donor included Specific donor requirements available on request and subject to additional fee	GMP compliant Collection Centers	Folsom, CA San Diego, CA Raleigh, NC Rockville, MD East Norriton, PA Cambridge, MA	Folsom, CA San Diego, CA Raleigh, NC Rockville, MD East Norriton, PA Cambridge, MA
Donor Consent	IRB-approved donor informed consent for further manufacture and commercialization Modifications subject to fee		FDA and CLIA registered Location specific donor recruitment available and subject to additional fees	FDA and CLIA registered Location specific donor recruitment available and subject to additional fees
Donor History	Donor History Questionnaire compliant with AABB DHQ for Hematopoietic Progenitor Cells (HPC- DHQ)	Catalogue Number	CG-LE010F	CG-PBCPD250F
Donor Physical Exam	Included		Includes Leukopak, standard donor screening and backup donor on-site	screening and backup on-site collection, standard donor screening and backup donor on-site
Donor Eligibility Screening	Performed within 7 days of collection FDA Licensed testing compliant with 21 CFR Part 1271 for donor eligibility and performed by CLIA licensed laboratory Full Panel details: •HIV I & II Ab + Reflex •HIV/HBV/HCV NAT •HCV Ab •HBV Ab Core + Reflex •HBV Ab Surface Ag + Reflex •HTLV I & II Ab + Reflex •Syphilis Ab •West Nile Virus NAT •T. Cruzi (Chagas) Ab •CMV Total with Reflex to IgM (Only performed if CMV total test result is positive) •CMV Total with Reflex to IgM and IgG/IgM (Only performed if CMV total test result is positive) •Zika NAT* inquire		Additional products and services quoted separately	Additional products and services quoted separately
		Description	Leukopak, Full collection, Fresh Clinical (GMP compliant)	Whole Blood, Fresh Clinical (GMP compliant)
		Anticoagulent	ACD-A	CPD available
		Cell Count / Volume / Viability	Target 10 Billion WBC Actual donor collection yield may vary ≥ 90% viability	250mL (CPD)
		Quality & Regulatory	QC and QA review and release of Summary of Record and Certificate of Analysis Performed under QMS controlled batch record and GMP compliant Inquire for addtl regulatory	QC and QA review and release of Summary of Record and Certificate of Analysis Performed under QMS controlled batch record and GMP compliant
			support	Inquire for addtl regulatory support
		Shipping	Validated shipping containers available	Validated shipping containers available
Additional Infectious Disease Testing	Available upon request and subject to additional fees	Price	Inquire for full project	Custom Inquire for full project questionnaire
HLA Testing, KIR Typing & other characterization	Available upon request and subject to additional fees			

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